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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:) Confirmation No.: 9828
)
Ricardo Alexander Gomez) Examiner: M. J. Kasztejna
)
Title: METHOD AND APPARATUS FOR) Group Art Unit: 3739
PROTECTING THE DISTAL LENS OF)
ENDOSCOPES)
)
Serial No.: 10/826,869)
)
Filed: April 16, 2004) (Our Docket No. 5285-0002)

Hartford, Connecticut, November 27, 2006

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APPEAL BRIEF IN ACCORDANCE WITH 37 C.F.R. §41.37

S I R:

This appeal is taken from the Final Office Action dated October 26, 2006 in
which claims 1-15 and 42 of the above-referenced application were rejected under
35 U.S.C. §102(b) and/or 35 U.S.C. §103(a).



I. REAL PARTY IN INTEREST

The real party in interest in the above-referenced patent application is:

Ricardo Alexander Gomez
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II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences of which Applicant is aware regarding the above-referenced application.

III. STATUS OF CLAIMS

Claims 1-15 and 42 are pending in this application. Claims 16-41 have been canceled. Claims 1-15 and 42 stand rejected under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 103(a). Rejected claims 1-15 and 42 are presented to the Board in this Appeal.

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention as recited in claim 1 resides in a sterile apparatus to protect endoscope(s). The apparatus includes an impact resistant housing (2) (See page 5, lines 18-20) having an outer surface defining an opening (1). (See page 6, lines 9 and 10). An interior of the housing (2) defines a canal (6) having a first end communicating with the opening (1) and a second end terminating within the housing (2) for receiving a distal lens of an endoscope. (See page 7, line 23 to page 8, line 5). A defogging material is disposed adjacent to the second

end of the canal (6) for defogging a distal lens of an endoscope when inserted within the canal (6). (See page 8, lines 13-19). A self-sealing mechanism is disposed within the canal (6). The self-sealing mechanism is configured to allow for an endoscope to enter the canal (6) and make contact with the defogging material and to prevent the defogging material from spilling out of the canal (6). (See page 8, line 21 to page 9, line 9).

The canal (6) can be shaped for receiving a plurality of types of endoscopes. For example, the canal (6) can be complementarily shaped to that of an endoscope to be received therein. (See page 6, lines 1-19).

The apparatus is preferably made of a disposable material (See page 5, lines 18-31), and configured to protect endoscopes during intermittent use and during transportation. (See Abstract, line 9).

The interior of the housing (2) preferably includes a storage sheath (6) defining the canal. The outer surfaces of the housing (2) and the storage sheath (6) define a cavity therebetween. An impact absorbing material preferably substantially fills the cavity. The impact absorbing material can be, for example, Styrofoam, a gel, a liquid, or a gas. (See page 5, lines 18-31).

The apparatus preferably includes means for removably affixing the housing (2) to a surface. For example, the apparatus can include an anchor (3), and a cord (4) attached to the housing (2) and the anchor (3). Moreover, the cord (4) can be removably attachable to the housing (2), and the anchor (3) can be removably attachable to a surface. (See page 6, lines 21-28).

The apparatus preferably includes a reservoir communicating with the second end of the canal (6) for accommodating the defogging material. (See page 8, lines 7-19).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues to be resolved are:

- (1) whether claims 1-7, 10-15 and 42 are anticipated under 35 U.S.C. § 102(b) by U.S. Patent Application Publication No. 2002/0022762 to Beane et al. (hereinafter "Beane et al.");
- (2) whether claim 8 is obvious under 35 U.S.C. § 103(a) over Beane et al. in view of U.S. Patent No. 5,720,391 to Dohm et al. (hereinafter "Dohm et al."); and
- (3) whether claim 9 is obvious under 35 U.S.C. § 103(a) over Beane et al. in view of U.S. Patent No. 6,910,582 to Lantz (hereinafter "Lantz").

VII. ARGUMENT

Rejection under 35 U.S.C. § 102(b) over Beane et al. (Ground 1)

Claims 1-7, 10-15 and 42

Claims 1-15 and 42 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Beane et al. Applicant respectfully submits that the Examiner's grounds of rejection are not well founded.

To anticipate a claim under 35 U.S.C. §102, a single reference must disclose each and every element of the claimed invention. Lewmar Marine Inc. v. Barient Inc., 3 U.S.P.Q. 2d 1766, 1767 (Fed. Cir. 1987). Absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

Beane et al. is directed to a lens warming and cleaning device for use with an optical surgical instrument. The device includes a heat-conducting tube sized and shaped to receive the lens portion of the instrument, a heating element thermally coupled to an exterior of the tube, and a cleaning member disposed within the tube. The cleaning member is disposed such that when the lens

portion of the instrument is inserted into the tube, the lens portion contacts the cleaning member.

Beane et al. does not teach or suggest a sterile apparatus to protect endoscopes wherein the apparatus includes a self-sealing mechanism disposed within a canal and configured to allow for an endoscope to enter the canal and contact defogging material and to prevent the defogging material from spilling out of the canal, as is generally recited in independent claim 1 and incorporated in dependent claims 2-7, 10-15 and 42. This is not surprising since Beane et al. teaches a saline solution retained in a sponge.

In support of the rejection, the Examiner states:

However, Beane et al. disclose the device wherein the distal end 124 is attached to bottle 118, and proximal end 122 is attached to a stem 126 on housing 112. Distal end attaches to bottle 118 via complementary screw threadings 128 (inside tube 114) and 130 (on bottle 118). Alternatively, bottle 118 and distal end 124 can be attached by an interference or press fit, using, e.g., an O-ring. Proximal end 122 is similarly attached to stem 126 using, e.g., complementary screw threadings, an insert mold, or an interference fit (see paragraph 0053). Thus, the interference or press fitting may consist of an O-Ring which would clearly be disposed within the tube, as seen in Figure 2a. The O-ring would act as a self-sealing mechanism as it is well known that O-rings are effective for forming seals. This self-sealing mechanism would further allow for an endoscope to enter the canal, as it clearly does not interfere with the endoscope from entering tube 114. Lastly, the solution of Beane et al. is retained in a sponge, however this is not suffice to say Beane et al. does not require a self-sealing mechanism as it is well known that sponges leak excess fluid

when saturated. Thus it would be obvious to use the self-sealing O-ring, as suggested by Beane et al., to ensure the defogging material does not spill out of the canal.

We do not understand and therefore disagree with the Examiner's grounds of rejection. The interference or press fit referred to by the Examiner merely has to do with how the walls of the bottle 118 and the tube 114 are attached to one another at a distal end 124 of the tube 114, and how the walls of the tube 114 and the housing 112 are attached at a proximal end 122 of the tube 114 . The interference or press fit has nothing to do with teaching a mechanism disposed within the tube 114 which would self-seal so as to obstruct and prevent fluid from spilling out of the tube. This is not surprising because Beane et al. does not need a self-sealing mechanism. The solution of Beane et al. is retained in a sponge. The present application lists examples of self-sealing mechanisms as, for example, a tube within a tube mechanism, valves including those resembling a heart valve or a valve in a human vein, a flap and hinge valve which opens only in one direction, and a ball and socket mechanism. (See page 8, line 21 to page 9, line 9).

An O-ring as taught by Beane et al. would be configured and implemented to hold together the walls of the bottle 118 and the tube 114, and possibly to prevent fluid from leaking through the walls of the bottle and tube where the ends of the walls are connected to one another. This O-ring is not configured or implemented to prevent fluid from escaping from the canal (i.e., through the canal opening).

For an anticipation rejection to be appropriate, each and every element or limitation in a rejected claim must be shown in a single prior art reference used in the claim rejection. Because Beane et al. does not teach or suggest a sterile

apparatus to protect endoscopes wherein the apparatus includes a self-sealing mechanism disposed within a canal and configured to allow for an endoscope to enter the canal and contact defogging material and to prevent the defogging material from spilling out of the canal, as is generally recited in independent claim 1 of the present application, it cannot be maintained that Beane et al. anticipates claim 1. Moreover, because claims 2-7, 10-15 and 42 each ultimately depend from and thereby incorporate the limitations of claim 1, these dependent claims are not anticipated by Beane et al. for at least the reasons set forth for claim 1.

Rejection under 35 U.S.C. §103(a) over Beane et al. in view of Dohm et al.

(Ground 2)

Claim 8

Claim 8 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Beane et al. in view of Dohm et al. Applicant respectfully submits that the Examiner's grounds of rejection are not well founded.

The legal determination under 35 U.S.C. § 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. Kahn v. General Motors Corp., 45 U.S.P.Q. 2d 1608, 1613 (Fed. Cir. 1998). An obviousness rejection based on a combination of selected elements in the prior art requires that there be some teaching, suggestion or motivation such that it would have been obvious to someone of ordinary skill in the pertinent art to make the specific combination made by the applicant. In re Kotzab, 55 U.S.P.Q. 2d 1313, 1316 (Fed. Cir. 2000); Winner Int'l Royalty Corp. v. Wang, 53 U.S.P.Q. 2d 1580, 1586 (Fed. Cir. 2000).

Dohm et al. is directed to packaging and a holder provided for a heart valve prosthesis. The holder is adapted to grasp the heart valve prosthesis and

includes a post. The packaging includes a collar for holding the post of the holder. An inner tray of the packaging receives the collar such that the prosthesis is suspended within the inner tray. An outer tray receives the inner tray. An inner tray lid seals the inner tray and an outer tray lid seals the outer tray.

The Examiner apparently cites Dohm et al. for mentioning that Styrofoam can be used for a transportation case for medical instruments. However, claim 8 ultimately depends from and thereby incorporates the limitations of independent claim 1 of the present application. It has been demonstrated above that Beane et al. contains insufficient teaching with regard to a self-sealing mechanism to anticipate claim 1. It therefore follows that Beane et al. also contains insufficient teaching with regard to a self-sealing mechanism when taken either alone or in combination with the Dohm et al. teaching on Styrofoam to render claim 8 obvious.

Rejection under 35 U.S.C. § 103(a) over Beane et al. in view of Lantz (Ground 3)

Claim 9

Claim 9 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Beane et al. in view of Lantz. Applicant respectfully submits that the Examiner's grounds of rejection are not well-founded.

Lantz is directed to a shock absorbing insulated shipping container including an external corrugated cardboard box, receiving an insulated body having a cavity for holding breakable glass bottles. The bottles may contain a high value liquid product being shipped, such as medicine or wine. The container also receives an especially configured and constructed, shock-absorbing filling structure or partition system for separating the glass bottles from one another, and from one or more receptacle cavities for holding phase change coolant or temperature control material in a predetermined relationship

to the glass bottles. The container also includes an insulating and cushioning cover adapted to engage into a top opening of the insulated body after the bottles and coolant are received in the cavity thereof. The insulated body is formed from injection molded polyurethane, wrapped in a plastic film.

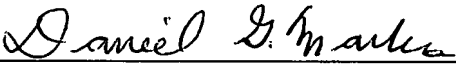
The Examiner apparently cites Lantz for mentioning that gel can be used for a transportation case for cushioning. However, claim 9 ultimately depends from and thereby incorporates the limitations of independent claim 1 of the present application. It has been demonstrated above that Beane et al. contains insufficient teaching with regard to a self-sealing mechanism to anticipate claim 1. It therefore follows that Beane et al. also contains insufficient teaching with regard to a self-sealing mechanism when taken either alone or in combination with the Lantz teaching on the cushioning effects of gel to render claim 9 obvious.

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In view of the foregoing, it is respectfully submitted that the rejections of claims 1-15 and 42 are not well-founded and therefore claims 1-15 and 42 should be allowed. Accordingly, Applicant respectfully requests this Board to reverse the Examiner's rejections and to allow the application under appeal to issue as a patent.

A check in the amount of \$250.00 is enclosed to cover the fee for filing an Appeal Brief for a small entity. No additional fees or deficiencies in fees are believed to be owed. However, authorization is hereby given to charge our Deposit Account No. 13-0235 in the event any such fees are owed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A sterile apparatus to protect endoscope(s) comprising:
 - an impact resistant housing having an outer surface defining an opening, an interior of the housing defining a canal having a first end communicating with the opening and a second end terminating within the housing for receiving a distal lens of an endoscope;
 - a defogging material disposed adjacent to the second end of the canal for defogging a distal lens of an endoscope when inserted within the canal; and
 - a self-sealing mechanism disposed within the canal, the self-sealing mechanism being configured to allow for an endoscope to enter the canal and make contact with the defogging material and to prevent the defogging material from spilling out of the canal.
2. An apparatus to protect endoscope(s) as in claim 1, wherein the canal is shaped for receiving a plurality of types of endoscopes.
3. An apparatus to protect endoscope(s) as in claim 1, wherein the apparatus is made of disposable material.
4. An apparatus to protect endoscope(s) as in claim 1, wherein the canal is complementarily shaped to that of an endoscope to be received therein.
5. An apparatus to protect endoscope(s) as in claim 1, wherein the apparatus is configured to protect endoscopes during intermittent use.

6. An apparatus to protect endoscope(s) as in claim 1, wherein the apparatus is configured to protect endoscopes during transportation.
7. An apparatus to protect endoscope(s) as in claim 1, wherein the interior of the housing includes:
 - a storage sheath defining the canal, the outer surface of the housing and the storage sheath defining a cavity therebetween; and
 - an impact absorbing material substantially filling the cavity.
8. An apparatus to protect endoscope(s) as in claim 7, wherein the impact absorbing material is Styrofoam.
9. An apparatus to protect endoscope(s) as in claim 7, wherein the impact absorbing material is a gel.
10. An apparatus to protect endoscope(s) as in claim 7, wherein the impact absorbing material is a liquid.
11. An apparatus to protect endoscope(s) as in claim 7, wherein the impact absorbing material is a gas.
12. An apparatus to protect endoscope(s) as in claim 1, further comprising means for removably affixing the housing to a surface.

13. An apparatus to protect endoscope(s) as in claim 1, further comprising:
an anchor; and
a cord attached to the housing and the anchor.
14. An apparatus to protect endoscope(s) as in claim 13, wherein the cord is
removably attachable to the housing.
15. An apparatus to protect endoscope(s) as in claim 13, wherein the anchor is
removably attachable to a surface.
42. An apparatus to protect endoscope(s) as in claim 1, further comprising a
reservoir communicating with the second end of the canal for accommodating
the defogging material.

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IX. EVIDENCE APPENDIX

NONE

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X. RELATED PROCEEDINGS APPENDIX

NONE